



# Aquatic Animal Drug Approval Workshop

## Overview, Introduction & Jargon

presented  
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# Presentation Topics



- ▶ **Workshop Objectives & Syllabus**
- ▶ **Who Are We?**
- ▶ **Glossary of Terms**
- ▶ **What Drug-use Assistance Can We Provide?**
- ▶ **The Drug Approval Process – Puzzle Overview**



# Workshop Objectives & Syllabus



## Objectives:

- 1. Provide you with an understanding of:**
  - ▶ what are INADs, what they can do for you, how can you participate
  - ▶ all legal drug use options and “best use” guidelines
  - ▶ the overall drug approval process and how INADs fit into “the puzzle”
  - ▶ who are the players in the drug approval process
    - ▶ what are AADAP’s primary functions
- 2. Encourage you to participate in AADAP’s INADs**



# Workshop Objectives & Syllabus

## Syllabus:

1. Introduction, overview and glossary of terms
2. Legal ways to use aquatic animal drugs
3. Drug-use regimens
4. Technical Presentations & videos
5. Steps to get a drug approved and the players
6. How INADs fit into the NADAs
7. AADAP's webpage and how it can help you
8. How and why to sign on with AADAP's INADs
9. How to complete the required INAD forms
10. An interactive lesson
11. Status of drug approvals
12. Wrap-up, review and recruiting



# Who are We?

- ▶ **AADAP = Aquatic Animal Drug Approval Partnership Program**
- ▶ **A distinct branch of the U.S. Fish & Wildlife Service's Division of the National Fish Hatchery System, located in Washington, DC**
  - ▶ **AADAP located in Bozeman, MT**
  - ▶ **An outgrowth of the FWS's National INAD Office and its associated National INAD Program (NIP)**
- ▶ **Mission: *to work with our partners to conserve, protect, and enhance the Nation's fishery resources by coordinating activities to obtain U.S. Food and Drug Administration approval for drugs, chemicals and therapeutants needed in aquaculture and fisheries management programs***



# Who are We?







# Important Acronyms & Definitions

## **NADA = New Animal Drug Application (Approval):**

- ▶ A formal application, accompanied by a defined suite of data sets, submitted to FDA's Center for Veterinary Medicine (CVM) by a drug company to demonstrate that its new drug is safe and effective
- ▶ estimated to take upwards of 10 years at a cost of \$10M or more
- ▶ public data necessary due to low profit incentive for drug companies

## **INAD = Investigational New Animal Drug exemption:**

- ▶ Exemption issued by the CVM to drug company or other entity allowing use of an unapproved drug under strict conditions
- ▶ Permits the generation of data to support an NADA
- ▶ Permits the release or slaughter of food animals treated with the experimental drug (i.e. "slaughter authorization")
- ▶ Permits the legal interstate transportation of the drug



# Important Acronyms & Definitions

## Technical Sections (TS) of an NADA:

- ▶ Any of the unique data sets comprising the NADA (up to 8)
- ▶ Combined, each TS provides the necessary documentation (i.e., proof) that the new drug is:
  - ▶ effective, as claimed on the label
  - ▶ safe to the target animal
  - ▶ safe for people to consume (in the case of food animals)
  - ▶ safe to the environment
  - ▶ safe to people involved in the manufacture, administration, etc.
  - ▶ manufactured in a manner to provide a consistent product, and hence, consistent results





# Important Acronyms & Definitions

## Pivotal Efficacy Studies (PES):

- ▶ Studies essential to the demonstration that the new drug works for the specified disease or condition in/on the species of fish as proposed in the label claim
- ▶ Strictly conducted (required components)
  - ▶ specified entrance and exit criteria
  - ▶ production or “quasi-production” setting; typically conducted by AADAP staff at your facility
  - ▶ non-treated controls
  - ▶ blinding of participants
  - ▶ CVM “approved” protocol
  - ▶ etc., etc., etc.....



# Important Acronyms & Definitions

## Supportive Efficacy Studies:

- ▶ Also referred to as collaborative, ancillary, or supplemental studies
- ▶ Studies needed to permit the label to be expanded to new species, and possible other claims (e.g., additional diseases or conditions)
- ▶ Not as strictly regulated/conducted as pivotal studies
  - ▶ conducted under AADAP INADs
  - ▶ AADAP INAD protocol followed (different from pivotal protocol)
  - ▶ production setting; conducted by facility's staff
  - ▶ non-treated controls desirable, but not essential
  - ▶ results provided to AADAP, who in turn, submit compiled results to CVM



# Important Acronyms & Definitions

## Withdrawal Period:

- ▶ That period of time from the last administration of any drug to the point at which a food animal may be harvested, stocked or caught
- ▶ Both approved drugs and investigational drugs have a well-defined withdrawal period, while drugs used under other conditions typically do not (e.g., veterinarian must determine for extra-label drugs)
- ▶ “Slaughter authorization” under an INAD is contingent upon compliance with withdrawal period
- ▶ Withdrawal period for an approved drug is typically less than that for the same drug pre-approval (i.e., under an INAD)



# Important Acronyms & Definitions

## Extra-Label Drug Use:

- ▶ Veterinarian prescription for the use of an approved drug for a disease, condition and/or species not on the approved label
  - ▶ Veterinary Feed Directive (VFD) drugs ineligible
  - ▶ pesticides and unapproved drugs ineligible
  - ▶ “conditionally approved” and “listed drugs” ineligible
    - ▶ legally available drug categories under the new Minor Use and Minor Species Drug Act of 2004
    - ▶ none currently exist – Federal Regulations incomplete
- ▶ Veterinarian must assume all responsibility for residues
- ▶ Authorized under Animal Medicinal Drug Use Clarification Act (AMDUCA)



# Important Acronyms & Definitions

## Veterinary Feed Directive:

- Written statement (prescription) issued by a licensed veterinarian that orders the use of a VFD drug in or on an animal feed
- Authorizes the client to obtain and use the VFD drug to treat their animal(s) as per directions for use approved by the FDA
- VFD can only be written if a valid veterinarian-client-patient relationship exists
- Aquaflor® (florfenicol) is the only approved aquaculture VFD drug
- Prior to VFD drugs, all approved medicated feed products for aquatic animals were available over the counter without a prescription



# How We Accomplish Our Mission

- ▶ Coordination of USFWS INADs via the NIP ★
  - ▶ NADA data development ★
  - ▶ NADA coordination
  - ▶ Information management/dissemination ★
  - ▶ USFWS Policy implementation
  - ▶ USFWS drug-use coordination
  - ▶ Partnership administration ★
- ★ = activities in which you can be directly involved and/or derive direct immediate benefit





# How We Accomplish Our Mission

- ▶ **Coordination of USFWS INADs**
  - ▶ **Interact with FDA: annual reports, new INADs, renewals, amendments**
  - ▶ **Interact with federal, state, tribal & private co-investigators ★**
  - ▶ **Interact with drug companies**
  - ▶ **Generate and revise research study & use protocols (PES & TAS, as they relate to next slide)**
  - ▶ **Maintain USFWS INAD administrative database ★**
  - ▶ **Host the Annual Drug Approval Coordination meeting ★**



# How We Accomplish Our Mission

- ▶ **NADA Data Development**
  - ▶ Pivotal effectiveness studies (PES) ★
  - ▶ Pivotal target animal safety (TAS) studies
  - ▶ Supportive effectiveness studies ★
  - ▶ Supportive target animal safety studies
  - ▶ Data compilation & Final Study Report (FSR) generation



# How We Accomplish Our Mission



- ▶ **NADA Coordination**
  - ▶ Overall NADA Technical Section coordination
  - ▶ Coordinate & administration of non-Service subcontracts ★
  - ▶ NADA Technical Section assembly
  - ▶ NADA Technical Section QA/QC
  - ▶ Interact with drug companies



# How We Accomplish Our Mission

- ▶ **Information Management**
  - ▶ USFWS INAD/NADA information website ★
  - ▶ USFWS INAD/NADA information quarterly newsletter ★
  - ▶ Aquatic Animal Drug Approval Partnership outreach ★

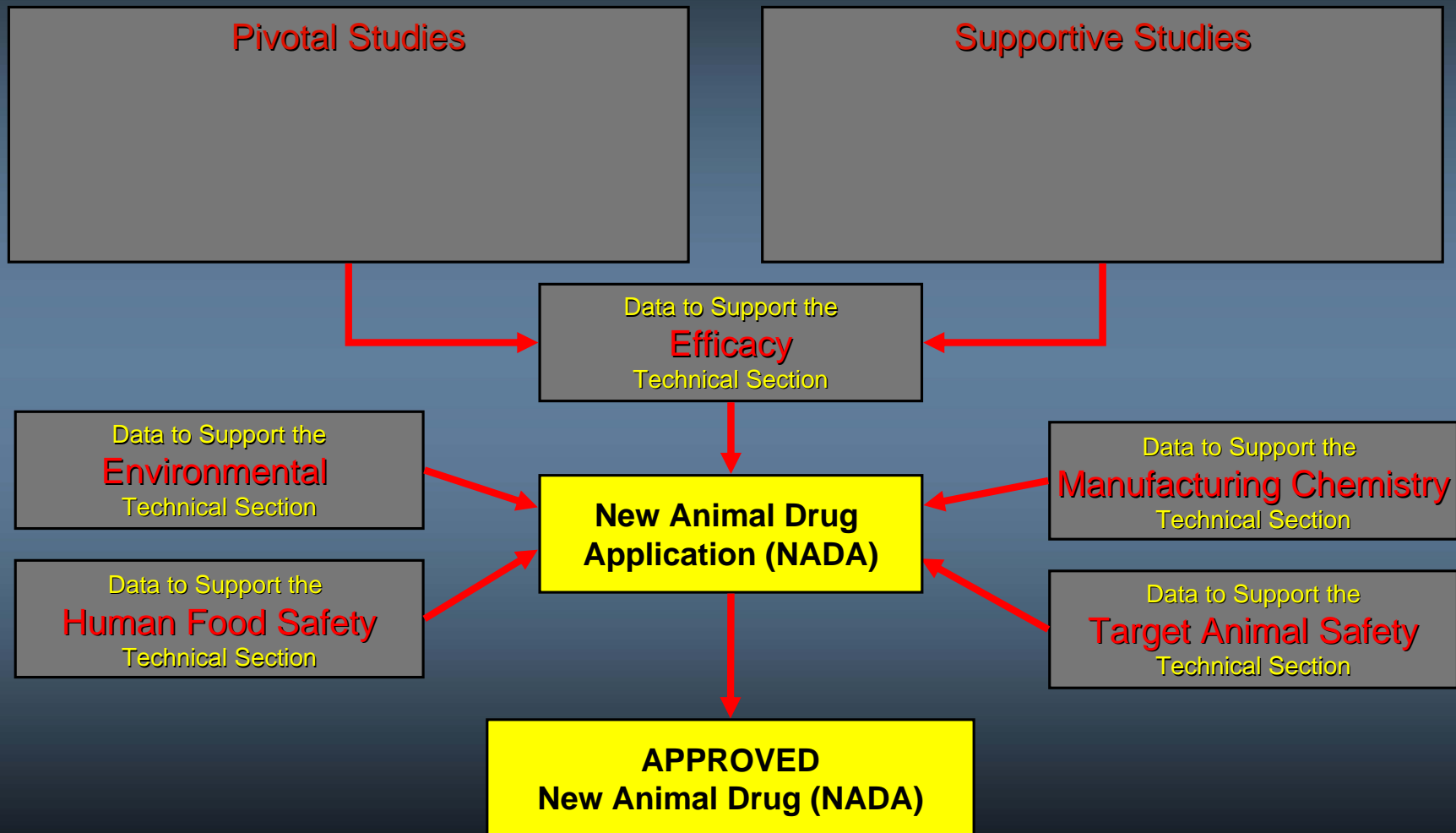


# What We Can Do for You

- ▶ Provide you with a means of legally using investigational drugs
- ▶ Allow you the opportunity to generate essential information for the broad approval of new aquatic animal drugs
  - ▶ your data will help ensure that the new approval includes the species of most interest to you
- ▶ Eliminate the headache of administering your own INAD
- ▶ Provide you with valuable information, via our website and newsletter, to better manage the overall health of your animals
- ▶ Give you a “bean” to count toward your partnering goal
- ▶ Act as an intermediary for discussion with drug companies, FDA, etc.



# The Drug Approval Process







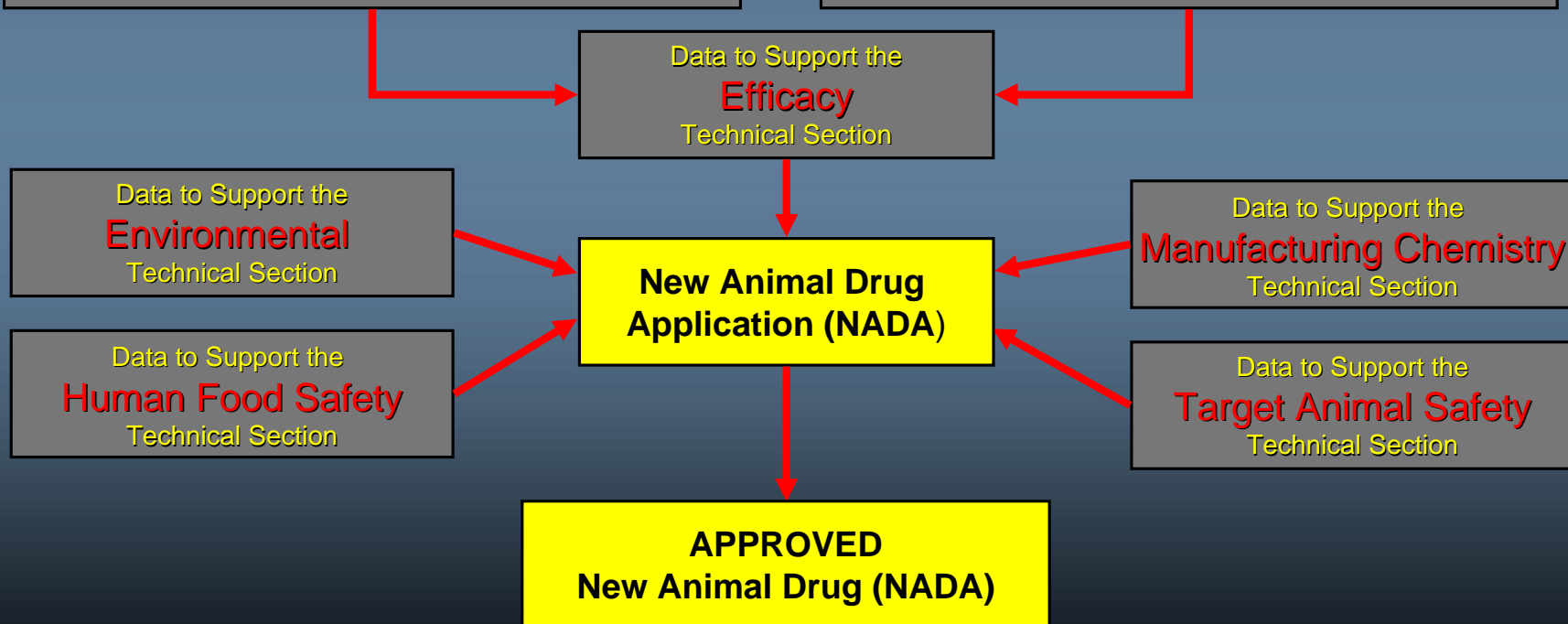
# The Drug Approval Process

## Pivotal Studies

- Required for Approval
- Limited number needed
- Studies are complex
- Conducted by AADAP, with your assistance at your facility

## Supportive Studies

- Not required for initial approval
- However, necessary for broader labels
- Studies are your production runs, conducted by you, under AADAP protocols





# Major Players in the Drug Approval Process

<b>Federal Agencies</b>	<b>Universities</b>	<b>Non-governmental Organizations or Entities</b>	<b>Drug Companies</b>
USFWS – Fish Health Ctrs.	Mississippi State Univ.	Pacific Northwest Fish Health Protection Comm.	Schering-Plough Animal Health
USFWS – AADAP	University of Florida	International Assoc. of Fish & Wildlife Agencies	AQUI-S New Zealand
USGS – Upper Midwest Environmental Sciences Ctr.	Southern Illinois Univ.	U.S. Joint Subcommittee on Aquaculture	Western Chemical, Inc.
USDA – Cooperative States Research Education and Extension Service	Michigan State Univ.	American Veterinary Medical Association	Akzo Nobel Chemicals, Inc.
USDA – Stuttgart National Aquaculture Research Ctr.	University of Idaho	National Coordinator for Aquatic New Animal Drug Applications	Phibro Animal Health
USDA – National Research Support Project No. 7	University of Arizona		Rangen, Inc.
USFDA – Center for Veterinary Medicine			Eka Nobel Chemicals, Inc.